

REMARKS

Claims 1, 4, 6, 10-16, and 39-44 were pending in the present application. New claims 45 and 46 have been added. Accordingly, upon entry of the amendments presented herein, claims 1, 4, 6, 10-16, and 39-46 will remain pending.

New claims 45 and 46 have been added to reflect particular embodiments of the invention, *i.e.*, nucleotide sequences having at least 95% identity to SEQ ID NO:1. Support for the new claims can be found throughout the application as filed, for example, at page 4, lines 2-6. *No new matter has been added.* Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Information Disclosure Statement

Applicants submit herewith a Supplemental Information Disclosure Statement with revised citations for each of references D1 and D2 (previously cited as C1 and C2). Applicants respectfully request that the Examiner consider references D1 and D2 as cited on the PTO Form SB-08 and acknowledge such consideration by initialing the PTO Form SB-08, as appropriate. With regard to the references cited in the specification, Applicants note that a Supplemental Information Disclosure Statement will be submitted shortly formally making those references of record.

Specification

The Examiner has repeated his objection to the disclosure because “[o]n page 28, lines 11-14, of the specification applicants state ‘As used herein, the term ‘hybridizes under stringent conditions’ is intended to describe conditions for hybridization and washing under which nucleotide sequences at least 60% homologous to each other typically remain hybridized to each other...’ Such a statement that nucleotide sequences which are 60% homologous would hybridize under stringent conditions is considered to be repugnant to what is known in the art.”

The Examiner further states that Applicants failed to respond to this objection in the Amendment and Response of March 24, 2004 and the Amendment and Response of December 16, 2004. Applicants did, in fact, respond in both Office

Actions. Specifically, in the Amendment and Response of March 24, 2004, Applicants stated that

Applicants respectfully traverse the foregoing objection to the specification. Applicants respectfully submit that the above statement is not repugnant to what is known in the art as evidenced by, for example, U.S. Patent No. 6,436,684, attached hereto as Appendix A. At column 26, lines 11-15, U.S. Patent No. 6,436,684 states that “[a]s used herein, the term ‘hybridizes under stringent conditions’ is intended to describe conditions for hybridization and washing under which nucleotide sequences encoding a peptide **at least 60-70% homologous** to each other typically remain hybridized to each other.” Therefore, Applicants respectfully submit that this statement was acceptable to those of ordinary skill in the relevant art at the time the application was filed.

For the convenience of the Examiner, Applicants re-submit herein a copy of U.S. Patent No. 6,436,684 as Appendix A. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing objection to the specification.

Claim Objections

Applicants note that the Office Action of January 31, 2005 erroneously includes a “Claim Objections” section. In accordance with Examiner Hutson’s instructions (provided in a June 30, 2005 voicemail), Applicants will disregard this section.

Rejection of Claims 6, 10-16 and 41-44 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 6, 10-16 and 41-44 under 35 U.S.C. § 112, first paragraph as not being sufficiently enabled. In particular, the Examiner is of the opinion that

...the specification, while being enabling for an isolated nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, and vectors and host cells comprising said nucleic acid, does not reasonably provide enablement for any isolated nucleic acid molecule [comprising] a nucleotide sequence at least 90% identical to the nucleotide sequence of SEQ ID NO: 1, wherein said nucleic acid molecule encodes a polypeptide which is capable of functioning as an extracellular nuclease, and vectors and host cells comprising said nucleic acid.

Applicants traverse the foregoing rejection as it pertains to claims 6 and 41, and claims depending therefrom, for the following reasons. Applicants would like to

bring to the Examiner's attention Example 14 of the *Revised Interim Written Description Guidelines Training Materials*. This example provides that a claim directed to variants of a protein having SEQ ID NO:3 "that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B" with an accompanying specification that discloses a single species falling within the claimed genus, satisfies the requirements of 35 U.S.C. §112, first paragraph for written description. The rationale behind the foregoing conclusion, as presented by the *Written Description Guidelines*, is that "[t]he single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which Applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity." The Guidelines also provide that "*[t]he procedures for making variants of SEQ ID NO:3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art.*"

Similarly, in the present case, claims 6 and 41, and claims depending therefrom, are directed to nucleic acid molecules that are at least 90% or 95% identical to SEQ ID NO:1, wherein the nucleic acid molecule encodes a polypeptide having extracellular nuclease activity. The indication in Example 14 of the *Written Description Guidelines* that the production of polypeptides which contain a 5% variation from a specific sequence is routine in the art can be equated with the production of nucleic acid molecules which contain a 5% variation from a specific sequence. Furthermore, Applicants have disclosed in the instant specification assays for identifying all of the at least 90% or 95% identical nucleic acid sequences of SEQ ID NO:1 that encode for a polypeptide having extracellular nuclease activity (see, for example, Examples 4-8 on page 51, line 32 through page 56, line 31 of the specification).

Based on the foregoing teachings in Applicants' specification, as well as the general knowledge in the art at the time of the claimed invention, one of skill in the art would be able to make and use the claimed invention using only routine experimentation. Accordingly, Applicants respectfully request reconsideration and

withdrawal of the rejection of claims 6, 10-16 and 41-44 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Applicants believe that the foregoing amendments and remarks render the application in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

A handwritten signature in black ink, appearing to read 'M. Laccotripe', written over a horizontal line.

Maria Laccotripe Zacharakis, Ph.D., J.D.
Registration No. 56,266
Attorney for Applicants

28 State Street
Boston, MA 02109
Tel. (617) 227-7400

Dated: **July 28, 2005**